Supreme Court, U.S.
FILED

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No. 99-

IN THE

Supreme Court of the United States

ABBOTT LABORATORIES,

Petitioner,

v.

MYLAN PHARMACEUTICALS, INC.,

Respondent.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

The Court of Appeals for the Federal Circuit summarily affirmed the District Court's determination that a United States Patent issued to petitioner Abbott Laboratories was invalid. The sole ground for the District Court's ruling, and the sole ground for the Court of Appeals' ruling, was collateral estoppel, for the same patent had been held invalid in a matter entitled *Abbott Laboratories v. Geneva Pharmaceuticals, Inc.*, 1998 WESTLAW 566884 (N.D. Ill. Sept. 1, 1998), *aff'd*, 182 F.3d 1315 (Fed. Cir. 1999) (hereinafter "*Geneva*").

Abbott Laboratories' petition for a writ of certiorari in the *Geneva* matter is presently pending before this Court (case no. 99-753). The issue presented by this petition, therefore, is: Should the Court accept review of this matter in order to preserve its ability to reverse the judgment if it reverses the judgment in the *Geneva* matter?

PARTIES TO THE PROCEEDING

The petitioner, Abbott Laboratories, was the plaintiff-appellant below. The respondent, Mylan Pharmaceuticals, Inc., was the defendant-appellee below. There are no other parties to this litigation. Abbott Laboratories' petition for a writ of certiorari is presently pending in a related case entitled *Abbott Laboratories v. Geneva Pharmaceuticals, Novopharm, Ltd. and Invamed, Inc.*, Supreme Court Case No. 99-753.

Petitioner Abbott Laboratories has no parent corporation, and no publicly held company owns 10% or more of its stock.

OPINIONS BELOW

The opinion of the United States Court of Appeals for the Federal Circuit is unreported and appears in Appendix A. The district court's unreported order granting summary judgment appears in Appendix B.

STATEMENT OF JURISDICTION

The opinion and order of the Court of Appeals was entered on October 4, 1999. The Court of Appeals' jurisdiction was based upon 28 U.S.C. § 1295(a)(1). The jurisdiction of this Court is invoked under 28 U.S.C. § 1254(1).

STATUTORY PROVISION INVOLVED

35 U.S.C. § 102 provides in relevant part:

> A person shall be entitled to a patent unless —
>
> * * *
>
> (b) the invention was . . . in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States. . . .

STATEMENT OF THE CASE

After scientists working at Abbott Laboratories (hereinafter "Abbott") discovered terazosin hydrochloride, a chemical compound useful for treating high blood pressure and enlargement of the prostate, Abbott was awarded a United States Patent covering that compound. Abbott scientists subsequently discovered that terazosin hydrochloride exists in different crystal forms, or polymorphs. Different polymorphs of a compound may vary in characteristics such

as density, hardness or solubility, and they have been found to be unique and patentable inventions. *See Zenith Laboratories v. Bristol-Myers Squibb Co.*, 19 F.3d 1418, 1419-20 (Fed. Cir.), *cert. denied*, 513 U.S. 995 (1994).

In the early 1990s, Abbott discovered a previously unknown polymorph of terazosin hydrochloride known as "Form IV." Abbott received United States Patent 5,504,207 ("the '207 patent") covering the Form IV polymorph on April 2, 1996. Abbott subsequently brought several suits against companies that had announced an intention to market a pharmaceutical product containing Form IV terazosin hydrochloride.

In one such case, *Abbott Laboratories v. Geneva Pharmaceuticals, Inc.*, nos. 96 C 3331, 96 C 5868, and 97 C 7587 (N.D. Ill. Aug. 28, 1998), the district court granted the defendants' motion for summary judgment and held Abbott's 207 patent to be invalid under section 102(b) of the Patent Act. The district court found that as a result of several transactions involving third parties, Form IV terazosin hydrochloride had been put on sale more than one year before Abbott filed its application for a patent on that compound. The court rejected Abbott's contention that section 102(b) was inapplicable where there was no evidence that any of the buyers, sellers or manufacturers of the chemical compound in question was aware that that compound consisted of a new and useful form of terazosin hydrochloride.

In an opinion and order entered on July 1, 1999, the Court of Appeals for the Federal Circuit affirmed the district court's entry of summary judgment. *See Abbott Laboratories v. Geneva Pharmaceuticals, Inc.*, 182 F.3d 1315 (Fed. Cir. 1999) (hereinafter "*Geneva*"). The Court of Appeals held that it was "irrelevant" under section 102(b) that "the parties to the sales transactions did not know they were dealing in Form IV at the time of the sales. . . ." *Id.* at 1318.

On October 29, 1999, Abbott Laboratories filed a petition for writ of certiorari in the *Geneva* matter. The petition contends that summary reversal or review by writ of certiorari is appropriate because the Court of Appeals' holding that the "on-sale bar" of section 102(b) was triggered by the *unknowing* manufacture and sale of a new chemical compound is in direct conflict with *Pfaff v. Wells Electronics, Inc.*, 525 U.S. 55, 119 S. Ct. 304 (1998). This Court held in *Pfaff* that the process of conception must be complete before the on-sale bar can arise. Abbott Laboratories' petition is presently pending (case no. 99-753).

In the instant case, the district court granted defendant's motion for summary judgment on March 4, 1999 and held Abbott's '207 patent to be invalid. The court's order was based entirely upon the collateral estoppel effect of the district court's judgment in the *Geneva* matter. Appendix B at 6a-7a. On October 4, 1999, the Court of Appeals for the Federal Circuit summarily affirmed the district court's entry of judgment. Appendix A at 2a. This petition followed.

REASONS FOR GRANTING THE WRIT

I.

IF THIS COURT GRANTS CERTIORARI IN THE *GENEVA* CASE, IT SHOULD GRANT CERTIORARI HERE IN ORDER TO ENSURE CONSISTENT RESULTS AND TO AVOID INJUSTICE.

The sole basis for the lower courts' holdings in this case was the collateral estoppel effect of the prior judicial decisions in the *Geneva* matter. If this Court grants Abbott's petition for writ of certiorari in *Geneva*, it should also grant review here to ensure that the judgment of invalidity in this case does not survive the reversal of the related judgment upon which it is based. Considerations of fairness and judicial

consistency strongly favor a grant of review under these circumstances. *See generally* Wright, Miller & Cooper, Federal Practice and Procedure: Jurisdiction, § 4433 (1981 ed.), at p. 313 (discussing the need to "achieve full protection against the grotesque result of perpetuating a judgment that rests on nothing more than a subsequently reversed judgment. . ." and recommending "a protective appeal in the second action that is held open pending determination of the appeal in the first action. . . .").[1]

---

1. If review is not granted here, Abbott Laboratories could, in the event of a reversal by this Court of the judgment in *Geneva*, file a motion in the Court of Appeals to recall its mandate in this matter and to remand the matter to the district court for further proceedings. *See, e.g., United States v. Tolliver*, 116 F.3d 120, 123-34 (5th Cir. 1997) (granting motion to recall mandate where Supreme Court had reversed convictions of moving party's co-defendants). In order to avoid the need for these further proceedings, however, the Court should grant the relief sought by this writ.

CONCLUSION

For the foregoing reasons, this writ should be granted.

Respectfully submitted,

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APPENDIX A — ORDER OF THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT DATED AND FILED OCTOBER 4, 1999

United States Court of Appeals for the Federal Circuit

99-1325

ABBOTT LABORATORIES,

Plaintiff-Appellant,

v.

MYLAN PHARMACEUTICALS, INC.,

Defendant-Appellee.

ON MOTION

Before LOURIE, RADER, and BRYSON, *Circuit Judges*.

BRYSON, *Circuit Judge*.

ORDER

Mylan Pharmaceuticals, Inc. renews its motion for summary affirmance of the judgment of the United States District Court for the Northern District of Illinois. Abbott Laboratories opposes.

Abbott appeals from the district court's decision granting summary judgment to Mylan and dismissing Abbott's claim of infringement against Mylan. The basis for the district

court's decision stemmed from a prior suit finding the patent at issue invalid, a finding that this court recently upheld on appeal. *See Abbott Laboratories v. Geneva Pharmaceuticals, Inc.*, 98-1593, -1594, -1595, 1999 U.S. App. LEXIS 14804 (Fed. Cir. July 1, 1999).

Summary affirmance of a case "is appropriate, *inter alia*, when the position of one party is so clearly correct as a matter of law that no substantial question regarding the outcome of the appeal exists." *Joshua v. United States*, 17 F.3d 378, 380 (Fed. Cir. 1994) (summarily affirming the Court of Federal Claims' dismissal of a complaint). Mylan contends that our decision in *Geneva* controls the outcome of the instant appeal. Abbott, in response to Mylan's renewed motion, primarily argues that the court should defer ruling on the motion until the court decides Abbott's petition for panel rehearing and rehearing en banc in *Geneva*. The court denied Abbott's petition in an August 5, 1999 order.

We agree with Mylan that our decision in *Geneva* controls the outcome of this appeal. Thus, because no substantial question exists regarding the outcome of the instant appeal, the court summarily affirms the judgment of the district court.

Accordingly,

IT IS ORDERED THAT:

(1) Mylan's renewed motion for summary affirmance is granted.

Appendix A

(2) Each side shall bear its own costs.

FOR THE COURT

OCT -4 1999
Date

s/ William C. Bryson
William C. Bryson
Circuit Judge

APPENDIX B — MEMORANDUM OPINION AND ORDER OF THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF ILLINOIS, EASTERN DIVISION DATED MARCH 4, 1999

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

No. 97 C 5450

ABBOTT LABORATORIES,
an Illinois corporation,

Plaintiff,

v.

MYLAN PHARMACEUTICALS, INC.,
a West Virginia corporation,

Defendant.

No. 98 C 1280

ABBOTT LABORATORIES,
an Illinois corporation,

Plaintiff,

v.

MYLAN PHARMACEUTICALS, INC.,
a West Virginia corporation,

Defendant.

Appendix B

MEMORANDUM OPINION AND ORDER

Plaintiff Abbott Laboratories ("Abbott") filed these two actions[1] for patent infringement against defendant Mylan Pharmaceuticals, Inc. ("Mylan") under 35 U.S.C. § 271(e)(2). Mylan moves for summary judgment, arguing that claim 4 of the patent is invalid.[2] For the reasons set forth below, the motion is granted.

Background

Since 1987, Abbott has sold terazosin hydrochloride, a drug for the treatment of hypertension,[3] under the trademark HYTRIN. In 1997, Mylan sought approval from the U.S. Food and Drug Administration ("FDA") to market a generic version of HYTRIN containing anhydrous terazosin hydrochloride.[4] Abbott claims the capsules Mylan seeks to

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1. Each of the suits, filed seven months apart, deals with a different dosage strength (or strengths) of the generic terazosin hydrochloride capsules that Mylan seeks approval to market (Case No. 97 C 5450, 5 mg; Case No. 98 C 1280, 1 mg, 2 mg and 10 mg). On May 5, 1998, the cases were consolidated pursuant to Fed. R. Civ. P. 42(a) and N.D. Ill. Local R. 2.31.

2. Mylan originally sought a ruling that claim 4 was both invalid and unenforceable. In a subsequent clarification, Mylan stated it seeks summary judgment based on invalidity only. (Def.'s Reply Br. in Supp. of Mot. for Summ. J. at 3.)

3. HYTRIN also is used in the treatment of benign prostatic hyperplasia.

4. Mylan's initial submission to the FDA requested approval to market 5 mg capsules. Subsequently, it amended its abbreviated new drug application ("ANDA") to include 1 mg, 2 mg and 10 mg dosage strengths as well.

market would infringe claim 4 of its U.S. Patent No. 5,504,207 ("the '207 patent"). However, Mylan contends claim 4 is invalid and that its capsules therefore would not infringe the '207 patent.

Collateral Estoppel

Claim 4, which claims a crystalline form of anhydrous terazosin hydrochloride (called Form IV), has already been held invalid. *Abbott Lab. v. Geneva Pharm., Inc.*, Nos. 96 C 3331, 96 C 5868, 97 C 7587, 1998 WL 566884, at *7 (N.D. Ill. Sept. 1, 1998) (Gottschall, J.) [hereinafter *Geneva*]. The invention at issue, Form IV terazosin hydrochloride, was found to be on sale more than one year before Abbott filed its application for the '207 patent. *Id.* Hence, claim 4 was held invalid under 35 U.S.C. § 102(b). *Id.*

A judgment of invalidity generally bars the patentee from relitigating the issue. *Blonder-Tongue Lab. v. University of Illinois Found.*, 402 U.S. 313, 330-34, 350 (1971); *Mississippi Chem. Corp. v. Swift Agric. Chemicals Corp.*, 717 F.2d 1374, 1376 (Fed. Cir. 1983). Unless the patentee can show she did not have a fair opportunity procedurally, substantively and evidentially to pursue her claim the first time, she is collaterally estopped from relitigating the validity question. *Blonder-Tongue*, 402 U.S. at 333; *Mississippi Chem.*, 717 F.2d at 1376, 1379. There is nothing here to indicate Abbott did not have such a full and fair chance to litigate its claim in *Geneva*.[5] *See Blonder-Tongue*, 402 U.S. at 333.

---

5. Abbott contends I should stay these proceedings until its appeal in *Geneva* is decided by the Federal Circuit. Abbott argues,

(Cont'd)

Appendix B

Accordingly, Mylan's motion for summary judgment is granted. There is no genuine issue of material fact as to the invalidity of claim 4 of the '207 patent, Fed. R. Civ. P. 56(c); *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986), and therefore no genuine issue as to whether Mylan's proposed product infringes that claim. It does not.

Conclusion

For the foregoing reasons, Mylan's motion for summary judgment is granted. Abbott is collaterally estopped from asserting the validity of claim 4 of the '207 patent.

ENTER ORDER:

s/ Elaine E. Bucklo
Elaine E. Bucklo
United States District Judge

Dated: March 4, 1999

(Cont'd)
inter alia, that such a stay would avoid any resulting inefficiency if *Geneva* were reversed, and thus would promote judicial economy. However, the *Blonder-Tongue* estoppel doctrine applies even when the earlier decision is on appeal. *Pharmacia & Upjohn Co. v. Mylan Pharm., Inc.*, 5 F. Supp. 2d 399, 407 (N.D.W.Va. 1998) (citing *Iron Ore Co. of Canada v. Dow Chem. Co.*, 177 U.S.P.Q. 34, 59_ (D. Utah 1972)). I decline to order a stay in this instance.

APPENDIX C — JUDGMENT OF THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF ILLINOIS, EASTERN DIVISION DATED MARCH 5, 1999

United States District Court
Northern District of Illinois
Eastern Division

Case Number: 98 C 1280
& 98 C 5450

Abbott Laboratories

v.

Mylan Pharmaceuticals, Inc.

JUDGMENT IN A CIVIL CASE

* * *

■ Decision by Court. This action came to hearing before the Court. The issues have been heard and a decision has been rendered.

IT IS HEREBY ORDERED AND ADJUDGED that pursuant to the Court's Memorandum Opinion and Order, judgment is entered and favor of defendant Mylan Pharmaceuticals, Inc. and against plaintiff Abbott Laboratories. Plaintiff Abbott Laboratories is collaterally estopped from asserting the validity of claim 4 of the '207 patent.

Appendix C

Michael W. Dobbins,
Clerk of Court

Date: 3/5/1999

s/ William J. Stasick
William J. Stasick,
Deputy Clerk

Supreme Court, U.S.
FILED
JAN 18 1999
CLERK

No. 99-1032

IN THE

Supreme Court of the United States

ABBOTT LABORATORIES,

Petitioner,

v.

MYLAN PHARMACEUTICALS INC.,

Respondent.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF IN OPPOSITION FOR MYLAN PHARMACEUTICALS INC.

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BEST AVAILABLE COPY

RESPONDENT'S STATEMENT UNDER RULE 29.6

Respondent Mylan Pharmaceuticals Inc. is a wholly-owned subsidiary of Mylan Laboratories Inc., which is a publicly-held company.

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TABLE OF AUTHORITIES

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Pfaff v. Wells Electronic, Inc.,
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RESPONDENT'S STATEMENT OF THE CASE

The United States District Court for the Northern District of Illinois granted summary judgment in this case based upon the collateral estoppel effect of a judgment of the same court in *Abbott Laboratories v. Geneva Pharmaceuticals, Inc.*, Nos. 96-C-3331, 96-C-5868, and 97-C-7587 (N.D. Ill. August 28, 1998). The District Court's unreported decision appears in Petitioners Appendix B. In *Geneva*, the District Court held that the only asserted claim of Abbott Laboratories' United States patent 5,504,207 ("the '207 patent") was invalid under 35 U.S.C. § 102(b), because the invention it claimed, Form IV terazosin hydrochloride, had been on sale more than one year before the effective filing date of the patent. The Federal Circuit affirmed the District Court's decision in *Geneva*. *Abbott Laboratories v. Geneva Pharmaceuticals, Inc.*, 182 F.3d 1315 (Fed. Cir. 1999). Abbott's motion for rehearing and its suggestion for a rehearing en banc were both denied.

Following the issuance of its opinion in *Geneva*, the Federal Circuit summarily affirmed the District Court's grant of summary judgment in this case based upon *Geneva*. The Federal Circuit's unreported opinion appears in Petitioner's Appendix A.

Abbott filed a petition for writ of certiorari in the *Geneva* case on October 29, 1999. On December 16, 1999, Abbott filed this petition for writ of certiorari contending that if its petition in *Geneva* were granted, it should be granted in this case as well "to ensure that the judgment of invalidity in this case does not survive the reversal of the related judgment." Petitioner's Brief at 3.

REASONS FOR DENYING THE WRIT

I. THIS COURT SHOULD NOT GRANT CERTIORARI IN *GENEVA* OR IN THIS CASE, HOWEVER IF CERTIORARI IS GRANTED IN *GENEVA*, THIS CASE SHOULD BE CONSOLIDATED WITH IT

For all of the reasons set forth in Geneva's brief in opposition to Abbott's petition for writ of certiorari, the courts below fully considered the issues and correctly applied the settled law, including this Court's own decision in *Pfaff v. Wells Electronic, Inc.*, 525 U.S. 55, 119 S. Ct. 304 (1998). Accordingly, this court should deny Abbott's writ in the *Geneva* case, thereby mooting the reason Abbott sets forth for granting its writ of certiorari in this matter. However, should this Court determine that it is appropriate to grant Abbott's writ of certiorari in *Geneva*, then pursuant to Rule 27(3) of the Rules of the Supreme Court of the United States, Respondent, Mylan Pharmaceuticals Inc., respectfully requests this Court to order that this case be consolidated with *Geneva* for argument as one case, because they involve the identical facts and questions of law.

CONCLUSION

For the foregoing reasons, Abbott's petition for writ of certiorari should be denied. However, in the event this Court grants Abbott's currently pending petition for certiorari in *Abbott Laboratories v. Geneva Pharmaceuticals, Inc.* (Case No. 99-753), Respondent requests that this case be consolidated with that case for purposes of oral argument

pursuant to Rule 27(3) of the Rules of the Supreme Court of the United States.

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